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09/590,211	06/08/2000	Guy A. Rouleau	3028.1000-000	9680

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

18

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/590,211

Examin r

Joseph T. Voitach

Applicant(s)

ROULEAU ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-17 and 19-39 is/are pending in the application.
- 4a) Of the above claim(s) 19-30 and 33-36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,11,13,14,16,17 and 37-39 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,31 and 32 is/are rejected.
- 7) ☒ Claim(s) 12 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1632

DETAILED ACTION

This application is a continuation of PCT/CA98/01133, filed December 7, 1998 which claims benefit to foreign application 2 218 199, filed December 9, 1997 in Canada.

Applicants' amendment filed June 24, 2003, paper number 17, has been received and entered. Claims 1, 3-5, 7-9, 11 and 12 have been amended. Claims 1, 3-9, 11-17, 19-39 are pending.

Election/Restriction

Applicant's election of Group I, claims 1-18, 31 and 32, in Paper No. 10 was acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13, -9, 11-17, 19-39 are pending. Claims 19-30 and 32-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10. Claims 1, 3-9, 11-17, 31, 32 and 37-39 are currently under examination.

Art Unit: 1632

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Specifically, the foreign application 2 218 199, filed December 9, 1997 in Canada has been received and entered as an attachment to paper 17.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims, 9, 11 and 12 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

The amendment to claim 9 has obviated the basis of the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1632

Claims 1, 3-8, 31 and 32 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants summarize the basis of the rejection and argue that a person of ordinary skill in the art cognizant of the present invention would readily recognize whether a potential variant was human or mouse (bottom of page 4). Further, issues raised with respect to 'allelic variants' are rendered moot by deletion of this recitation from the claims. Finally, Applicants argue that other genetic elements associated with the PABII gene are adequately described pointing to figure 1B for support of adequate description. See Applicants' amendment bridging pages 4-5. Applicants' arguments have been fully considered and found persuasive in part.

Examiner agrees that deletion of the term 'an allelic variant' and amending the claim to encompass the 'polymorphic repeat' has addressed this specific portion of the rejection. However, the claims recite open language and still encompass the entire PAB II gene, and broadly any potential allelic variant which may exist or which could be created though the term has been deleted. Applicants argue that one could distinguish between human and mouse sequences, however fail to specifically indicate the basis of this statement. As noted in the previous office action, the two sequences specifically disclosed are highly homologous differing in only one base pair. It is unclear how one could conclusively define a given gene sequence as human or mouse or simply as some allele of either. Applicant's arguments fail to comply with 37

Art Unit: 1632

CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them. Further, a graphic depiction of a gene structure fails to provide adequate structural or functional features of the polynucleotide encompassed by the claimed invention. The written description of a claim is evaluated on the basis of the claimed invention as a whole. Case law established that the requirement for written description relates to the subject matter defined by the claims. *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989). To this end, while the individual elements encompassed by a gene may be generally acknowledged in the art, none of these elements have been considered to be conventional or specifically known given a limited disclosure of only a portion of the complete gene sequence. The specification fails to demonstrate possession of the invention by actual reduction to practice, clear depiction of the invention in a detailed drawing, or description with sufficient relevant identifying characteristics (of the invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. It is maintained that the skilled artisan cannot envision the detailed structure of the claimed PAB II gene including any variant isolated from any human encompassed by the instant claims, and thus, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method required to generate such sequences. Case law has established that one cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483.

Art Unit: 1632

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, 11 and 12 previously rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Amendments to the claims has obviated the basis of each of the previous rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-9, 11-17, 31, 32 and 37-39 rejected under 35 U.S.C. 102(a) as being anticipated by Brais *et al.* is withdrawn.

The filing of the certified copy of foreign application 2 218 199 has perfected the claim for foreign priority. Accordingly, Brais *et al.* no longer qualifies as a 102(a) type reference.

Art Unit: 1632

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 1 be found allowable, claims 4 and 7-9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 4 simply states that the gene is dominant and claims 7-9 only describe the source of the sequence. In both cases neither limitation further limits the sequences set forth in claim 1.

Art Unit: 1632

Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 9 and 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the limitation set forth in claim 12 does not further limit the sequences encompassed by claims 9 and 11.

Claim 15 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 13 and 14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the limitation set forth in claim 15 does not further limit the sequences encompassed by claims 13 and 14.

Conclusion

Claims 9, 11, 13, 14, 16, 17 and 37-39 are allowed. Claims 1, 3-8, 12, 15, 31 and 32 are free of the art of record, however they are subject to other objections and rejections.

Art Unit: 1632

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.



Joseph T. Woitach

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800-1630